

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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November 2, 2016

VIA EMAIL AND FIRST CLASS MAIL

The Honorable Loretta Lynch
Attorney General
c/o Office of Legislative Affairs
U.S. Department of Justice
950 Pennsylvania Ave NW
Washington, DC 20530

Dear Attorney General Lynch:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the “Panel”) and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the practices of entities that procure and transfer fetal tissue.

Over the course of our investigation, we have uncovered documents and received testimony from confidential informants indicating that StemExpress, LLC (“StemExpress”), a firm that procures fetal tissue from abortion clinics and transfers it to research customers, violated various provisions of federal and state law, including but not limited to 42 U.S.C. § 289g-2 and Cal. Penal Code § 367f, which forbid the transfer of fetal tissue for valuable consideration.

StemExpress’ Business Model and Growth Strategy

StemExpress was founded in 2010 as a for-profit company and continues operations as StemExpress Foundation. Under its business plan, StemExpress recruited and screened clinics that were most likely to perform abortions that could produce saleable tissue to researchers.¹ The company sought information about the number of abortions the clinics performed each week, the gestational age of fetuses scheduled to be aborted, the days the abortions were done, whether

¹ StemExpress Website Recruitment Form for Abortion Clinics, attachment 1.

digoxin² was used (which would taint the tissue and, thus, render the baby useless for obtaining tissue), and, if so, at what age it was used. Researchers ordered tissue using StemExpress' website. The firm initially had a drop-down menu that allowed researchers to obtain various types of tissue.³ It later switched to another web-based system.

In order to harvest the tissue, StemExpress embedded tissue technicians inside the abortion clinics. Evidence uncovered by the Panel indicates females were recruited as tissue technicians to facilitate the consent process. The technicians' typical work day went as follows:

- At the beginning of the day, the tissue technician received an email from StemExpress including the day's orders for certain baby body parts and the gestation period, letting her know what she needed to harvest that day, and where she would be assigned.
- Once she arrived at the clinic, the tissue technician checked in with the Abortion Clinic Assistant Manager and informed the staff what she would procure that day.
- Then the technician reviewed the private medical files of the patients for that day to learn their names and the gestational ages of their babies. She recorded the gestations on the gestation tracking log provided by StemExpress.
- Next the technician met with the patients waiting to be prepped for their abortions, after receiving their names from clinic staff. Then she convinced them to consent to donate by saying that the donation will help cure diabetes, Parkinson's, and heart disease.⁴
- After an abortion, the technician collected the baby's remains and procured the body parts that were ordered, using her own supplies.⁵ The technician then packed the tissues or body parts, and shipped them directly to the customer via a courier or FedEx.
- She received an hourly wage and a bonus for each tissue, illustrated in the attached pay rate and bonus chart.⁶

StemExpress' stunning revenue growth five years after its formation belies the notion that the firm was not operating for profit. In 2010, its revenue was \$156,312; during 2011, that figure more than doubled to \$380,000; a year later, in 2012, StemExpress' revenue nearly tripled to \$910,000; by 2013, its revenue was \$2.20 million; then in 2014, the revenue had once again more than doubled to \$4.50 million. Based on its three-year revenue growth of 1,315.9%, *Inc. Magazine* named StemExpress one of the fastest-growing privately held companies in the U.S.⁷

² Digoxin is a heart medication that sometimes is injected into the amniotic fluid or fetus to cause fetal demise before surgical or induction abortion. *See* Abortion in California: A Medical-Legal Resource, available at http://californiaabortionlaw.com/wp/?page_id=135.

³ StemExpress Drop-Down Ordering Menu, attachment 2.

⁴ BioMed IRB Informed Consent to Participate in a Clinical Research Study, Sponsor: StemExpress, LLC, attachment 3.

⁵ *See* Standard Operating Procedure, Jan. 24, 2011, at 1 ("The clinic staff will identify donors"), attachment 4.

⁶ StemExpress Embedded Technician Pay Rates and Bonuses, attachment 5.

⁷ *The 500: Get to know the 500 fastest-growing privately held companies in America*, INC., Sept. 2014, at 137.

This revenue growth accompanied an aggressive marketing strategy directed toward abortion clinics. StemExpress distributed its brochure at a conference hosted by the National Abortion Federation (NAF). The brochure promised clinics they would be “[f]inancially profitable” if they allowed StemExpress to procure tissue from the clinics. The brochure also said “By partnering with StemExpress” the clinics will not only help research “but [they] will also be contributing to the fiscal growth of [their] own clinic[s].”⁸

When StemExpress was formed, billing records show the firm was procuring fetal tissue from four clinics. By the end of 2014, the firm had “relationships with more than 30 procurement sites across the country.”⁹ However, many of those procurement sites had multiple clinics, making the actual number nearly 100. In 2015, StemExpress tried to execute a contract with NAF that would have given the firm potential access to nearly 200 additional clinics. Its overall strategy was to provide on-demand body parts to researchers. In order to do that, the firm needed a ready supply of fetal tissue. The only way to achieve that was to dramatically increase the number of abortion clinics from which it would obtain fetal tissue.

StemExpress’ Profit and Loss

Attached is a sample of a StemExpress invoice to a customer.¹⁰ According to the accounting records obtained by the Panel, StemExpress paid approximately \$55 for each fetal tissue sample or Product of Conception (POC) it obtained from abortion clinics and transferred it to researchers for up to \$595 to \$890 per tissue or body part. The following charts summarize payments StemExpress made to abortion providers to obtain fetal tissue and those it received from its customers for such tissue.

Payments from StemExpress to Abortion Providers

CLINIC	DATE	ITEM	COST
Camelback Family Planning	2015	[not specified]	\$600
Camelback Family Planning	2015	[not specified]	\$600
			Total: \$1,200
Cedar River Clinic	2015	Amniotic	\$100.00
Cedar River Clinic	2013	Blood Samples	\$960.00
Cedar River Clinic	2014	Blood Samples	\$2,600.00
Cedar River Clinic	2014	Femur	\$125.00
Cedar River Clinic	2015	Femur	\$75.00
Cedar River Clinic	2014	Fetal Indications	\$7,250.00
Cedar River Clinic	2015	Fetal Indications	\$4,250.00
Cedar River Clinic	2014	Gift Cards	\$10,650.00

⁸ StemExpress Brochure Distributed at NAF Conference, attachment 6 (key text highlighted).

⁹ Complaint at para. 17, StemExpress, LLC v. Center for Medical Progress, No. BC-589145 (L.A. Super. Ct. filed Jul. 27, 2015).

¹⁰ Sample StemExpress Invoice to Customer, attachment 7.

Cedar River Clinic	2015	Gift Cards	\$10,250.00
Cedar River Clinic	2015	Hotel	\$92.00
Cedar River Clinic	2014	Kit	\$625.00
Cedar River Clinic	2015	Liver	\$125.00
Cedar River Clinic	2014	Maternal Blood	\$1,400.00
Cedar River Clinic	2014	Maternal Blood	\$350.00
Cedar River Clinic	2014	Maternal Blood	\$28,675.00
Cedar River Clinic	2015	Maternal Blood	\$8,700.00
Cedar River Clinic	2014	Maternal Blood	\$650.00
Cedar River Clinic	2015	Maternal Blood	\$100.00
Cedar River Clinic	2014	Maternal Blood/Tissue Kit	\$35,550.00
Cedar River Clinic	2015	Maternal Blood/Tissue Kit	\$39,225.00
Cedar River Clinic	2015	Maternal Blood	\$250.00
Cedar River Clinic	2015	Peripheral Blood	\$6,350.00
Cedar River Clinic	2015	Rental Car	\$167.98
Cedar River Clinic	2015	Thymus	\$75.00
Cedar River Clinic	2014	Tissue	\$225.00
Cedar River Clinic	2014	Tissue	\$75.00
Cedar River Clinic	2015	Tissue Brain	\$75.00
Cedar River Clinic	2015	Tissue Liver	\$250.00
Cedar River Clinic	2014	Tissue Only	\$500.00
Cedar River Clinic	2015	Tissue Only	\$75.00
Cedar River Clinic	2015	Tissue Pancreas	\$75.00
Cedar River Clinic	2015	Trisomy credit	\$200.00
Cedar River Clinic	2014	Whole Blood	\$12,850.00
Cedar River Clinic	2015	Whole Blood	\$8,400.00
			Total: \$181,319.98
Family Planning Specialist	2011	Blood Draws	\$1,090.00
Family Planning Specialist	2012	Blood Draws	\$5,325.00
Family Planning Specialist	2011	Specimen	\$440.00
Family Planning Specialist	2012	Specimen	\$6600
			Total: \$13,455.00
Mar Monte	2010	Blood	\$1,700
Mar Monte	2011	Blood	\$33,153
Mar Monte	2012	Blood	\$31,380
Mar Monte	2013	Blood	\$16,080
Mar Monte	2014	Blood	\$14,640
Mar Monte	2015	Blood	\$3,190
Mar Monte	2010	POC	\$1,210
Mar Monte	2011	POC	\$15,235

Mar Monte	2012	POC	\$43,245
Mar Monte	2013	POC	\$24,140
Mar Monte	2014	POC	\$25,990
Mar Monte	2015	POC	\$13,355
			Total: \$223,318.00
Presidential Women's Center	2014	Blood	\$6,450.00
Presidential Women's Center	2015	Blood	\$4,455.00
Presidential Women's Center	2014	Tissue Liver	\$1,425.00
Presidential Women's Center	2015	Tissue Liver	\$675.00
Presidential Women's Center	2015	Tissue Villi	\$75.00
Presidential Women's Center	2015	Tissue Villi	\$150.00
Presidential Women's Center	2015	Tissue Villi	\$525.00
Presidential Women's Center	2014	Tissue Villi	\$75.00
Presidential Women's Center	2015	Tissue Villi	\$1,800
Presidential Women's Center	2015	Tissue Villi Twin a	\$75.00
Presidential Women's Center	2015	Tissue Villi Twin b	\$75.00
			Total: \$15,780.00
Shasta Pacific	2012	Blood	\$650.0
Shasta Pacific	2013	Blood	\$4,470.00
Shasta Pacific	2014	Blood	\$2,530.00
Shasta Pacific	2015	Blood	\$100.00
Shasta Pacific	2012	POC	\$1,870.00
Shasta Pacific	2013	POC	\$3,960.00
Shasta Pacific	2014	POC	\$6,160.00
Shasta Pacific	2015	POC	\$715.00
			Total: \$20,455.00
			GRAND TOTAL: \$455,527.98

Payments from Customers to StemExpress for Fetal Tissue

CUSTOMER	YEAR	TOTAL PAYMENTS
All Cells	2011	\$4,040
Columbia University	2011	\$540
Colorado State University	2011	\$2,700
Dartmouth	2011	\$3,240
Drexel University	2011	\$3,510
Johns Hopkins	2011	\$1,950
Ohio State University	2011	\$235
Stanford University	2011	\$28,650
University of California – Los Angeles	2011	\$3,920
University of Connecticut	2011	\$930
University of Massachusetts Medical School	2011	\$43,115
Vanderbilt University Medical Center	2011	\$2,700
Yale College of Medicine	2011	\$390
Zyagen	2011	\$3,910
All Cells	2012	\$5,680
Baylor College of Medicine	2012	\$2,500
Columbia University	2012	\$2,925
Colorado State University	2012	\$1,220
Dartmouth	2012	\$4,160
George Washington University	2012	\$435
Johns Hopkins	2012	\$1,680
Massachusetts General Hospital	2012	\$3,000
Stanford University	2012	\$32,385
University of California – Los Angeles	2012	\$9,370
University of Connecticut	2012	\$1,110
University of Massachusetts Medical School	2012	\$32,290
Vanderbilt University Medical Center	2012	\$7,460
Yale College of Medicine	2012	\$6,825
University of North Carolina	2012	\$720
University of Illinois at Chicago	2012	\$250
All Cells	2013	\$3,920
Baylor College of Medicine	2013	\$1,000
City of Hope	2013	\$350
Columbia University	2013	\$750
Colorado State University	2013	\$2,250
Dartmouth	2013	\$500
Ganogen, Inc.	2013	\$6,825
Harvard	2013	\$6,680
Massachusetts General Hospital	2013	\$7,125
Rockefeller University	2013	\$250

Stanford University	2013	\$16,065
Thomas Jefferson University	2013	\$500
University of California – Los Angeles	2013	\$9,000
University of Connecticut	2013	\$500
University of Illinois at Chicago	2013	\$16,750
University of North Carolina	2013	\$1,750
University of Pennsylvania	2013	\$2,750
Vanderbilt University Medical Center	2013	\$3,000
City of Hope	2014	\$595
Ganogen, Inc.	2014	\$795
Medical College of Wisconsin	2014	\$2,380
Stanford University	2014	\$42,535
University of Massachusetts Medical School	2014	\$2,380
Vanderbilt University Medical Center	2014	\$595
Children’s Hospital of Philadelphia	2015	\$1,190
City of Hope	2015	\$595
Neurona Therapeutics	2015	\$1,190
Stanford University	2015	\$20,670
University of Massachusetts Medical School	2015	\$595
Zyagen, Inc.	2015	\$3,578

A more detailed breakdown of these tissue payments is attached hereto.¹¹

Attorneys for StemExpress created several cost estimates that purport to show that StemExpress loses money each time it procures a fetal tissue sample and ships it to a customer, but the Panel’s staff conducted an analysis of those estimates. A comparison of invoices, attorney-created accounting documents purporting to state costs, and productions from multiple StemExpress customers shows that the firm likely made a profit when procuring and transferring fetal tissue. Attached hereto¹² is a component of the Panel’s analysis, which shows StemExpress overstated some of its labor costs and claimed as expenses shipping, supplies, and infectious disease screenings. These were costs charged to researchers.

Violation of Applicable Laws

Under 42 U.S.C. § 289g-2, it is unlawful for any person to “knowingly acquire, receive, or otherwise transfer any fetal tissue for valuable consideration if the transfer affects interstate commerce.”¹³ The term “‘valuable consideration’ does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.”¹⁴ Anyone who violates this law is subject to a fine “not less than

¹¹ List of StemExpress Fetal Tissue Sales by Customer, 2011-2015, attachment 8.

¹² Select Panel Analysis of StemExpress Statement of Costs, attachment 9.

¹³ 42 U.S.C. § 289g-2(a).

¹⁴ 42 U.S.C. § 289g-2(e)(3).

twice the amount of the valuable consideration received” and/or imprisonment for up to ten years.¹⁵

California state law includes a nearly identical prohibition. Under Cal. Health & Safety Code § 125320(a), a “person may not knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes.” The California statute’s definition of “valuable consideration” is virtually identical to that of the federal statute.¹⁶ Similar provisions in the California Penal Code § 367f(a) prohibit the acquisition, sale, or transfer of “any human organ, for purposes of transplantation, for valuable consideration,” subject to a fine of up to \$50,000 and imprisonment for up to five years.¹⁷

The foregoing analysis establishes with a high level of probability that StemExpress and the clinics and research institutions with which it contracted routinely violated 42 U.S.C. § 289g-2 and Cal. Health & Safety Code § 125320(a). This is established generally by the company’s aggressive growth strategy, which explicitly included the goal of generating profit, and specifically by the transactions involving the transfer of fetal tissue to and from numerous entities for consideration that exceeded statutorily allowable costs. To the extent any of these transactions occurred for purposes of transplantation, StemExpress and any business partners so involved would additionally be in violation of California Penal Code § 367f(a).

The Panel’s investigation additionally revealed indicates that StemExpress and Planned Parenthood Mar Monte (PPMM), Planned Parenthood Shasta Pacific (PPSP), and Family Planning Specialists Medical Group (FPS) committed systematic violations of the HIPAA Privacy Rule from about 2010 to 2015. During that time, the aforementioned clinics, which are “covered entities” under HIPAA, permitted employees of StemExpress, a noncovered entity, to enter their clinics and procure human fetal tissue from aborted infants, obtain PHI about their patients, interact with patients, and seek and obtain patient consent for tissue donation. StemExpress did not have a medically valid reason to see, and the abortion clinics did not have a reason to provide, patients’ PHI. Instead, the clinics shared patients’ PHI with StemExpress in furtherance of contractual agreements that financially benefited both sides of the respective contracts. StemExpress employees were routinely handed a patient’s medical chart by her healthcare provider, in blatant violation of the HIPAA privacy rule.

These clinics and StemExpress violated the HIPAA privacy rule because: (a) the disclosures of patients’ PHI made by the abortion clinics and received by StemExpress were neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye or tissue transplantation or for research; (b) the consents for fetal tissue donation ostensibly obtained by StemExpress from the abortion clinics’ patients did not constitute sufficient authorizations for the disclosure of PHI; (c) the disclosures of patients’ PHI made by the abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants; and (d) StemExpress is not a business associate of the abortion clinics under HIPAA.

¹⁵ 42 U.S.C. § 289g-2(d).

¹⁶ Such consideration “does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of a part.” Cal. Health & Safety Code § 125320(b).

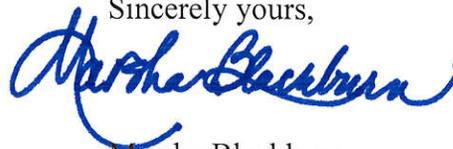
¹⁷ Cal. Penal Code §§ 367f(a), (g).

The abortion clinics could have directly consented their patients for tissue donation and entered an agreement with StemExpress to provide a limited data set regarding the patients they were seeing on a particular day.¹⁸ Instead, they violated the Privacy Rule by permitting StemExpress to view the most intimate information about their patients. These disclosures made by the abortion clinics to StemExpress were intentional and purposeful.¹⁹ The Panel made a referral of each of these entities to the Department of Health and Human Services, and requested a swift and full investigation by the HHS Office of Civil Rights. A copy of this referral detailing the foregoing facts is attached hereto.²⁰

Also relevant are the federal regulations governing consent prior to the acquisition of fetal tissue. Under 45 C.F.R. § 46, the Department of Health and Human Services requires investigators to obtain informed consent from each human being used as a research subject.²¹ The rule lists several criteria for Institutional Review Board (“IRB”) approval, including the requirement that researchers obtain the informed consent from their research subjects. As was demonstrated in the Panel’s referral to the Secretary of Health and Human Services, attached hereto,²² StemExpress’ procurement of fetal tissue from abortion clinics and transfer thereof to research customers violated 45 C.F.R. § 46: The company devised the appearance of compliance with the regulations while fraudulently using invalid consent forms and misleading customers to believe it had a valid IRB approval.

Based on the facts outlined above and the supporting documentation, I urge your office to conduct a thorough investigation into whether StemExpress violated these statutes and regulations, and, if you agree that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact Frank Scaturro, at (202) 225-2927, Frank.Scaturro@mail.house.gov, or Mary Harned, at (202) 480-7160, Mary.Harned@mail.house.gov.

Sincerely yours,



Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

¹⁸ See 45 C.F.R. § 164.514(e).

¹⁹ See 45 C.F.R. § 164.502(a)(1)(iii).

²⁰ Letter from Rep. Marsha Blackburn, Chair, Select Investigative Panel, to Jocelyn Samuels, Director, Centralized Case Management Operations, Department of Health and Human Services, June 1, 2016, attachment 10.

²¹ 45 C.F.R. § 46.116.

²² Letter from Rep. Marsha Blackburn, Chair, Select Investigative Panel, to Jerry Menikoff, Director, Office for Human Research Protections, Department of Health and Human Services, June 1, 2016, attachment 11.

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel

The Honorable Vern Pierson
El Dorado County District Attorney